Chas. Hude
Patents · Trade Marks · Designs



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Via fax No +49 89 2399 4465 - 22 pages
Confirmation copy via Courier

6 October 2005

Dear Sirs

International patent application No PCT/EP2004/013963
Applicant: Cadbury Schweppes PLC
International classification: IPC A61K7/16, A23G3/00
My ref: 80081 MBE/UCK/TR

The European Patent Office is hereby requested to carry out a detailed preliminary examination according to the enclosed DEMAND.

The official fee for the examination should be deducted from my account as per the enclosed fee calculation sheet.

In reply to the Written Opinion of the International Search Authority dated 9 May 2005, please find below the Applicant's comments thereto as well as an amended set of claims.

Amended claims:

The claims have been amended as follows:

Claim 1 has been amended such that the broad term "confectionary" has been specified and replaced by the more narrow term "lozenge". Basis for this specification can be found in e.g. originally filed claim 16. Furthermore, in claim 1, the tooth whitening agent has been specified to com-

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prise calcium pyrophosphate. Basis for this amendment can be found e.g. in the originally filed claim 2. Accordingly, original claims 2 and 16 have been deleted. Claim 5 has been amended in accordance herewith. The remaining claims have been renumbered in accordance herewith.

Present claims 19 – 21 (original claims 21 – 23) have been amended such that the broad term "confectionary" has been specified and replaced by the more narrow term "lozenge" in accordance with the amendments of claim 1.

Prior art cited:

In reply to the citations mentioned in the written opinion, the Applicant has the following comments:

**D1** (WO 03/002056) relates to oral compositions comprising cetyl pyridinium chloride as an antibacterial agent. The objective problem solved hereby relates to the inhibition of the formation of plaque, oral malodour, gingivitis, periodontal disease and the like. Among several others, "lozenge" (p. 5 l. 16) is mentioned as an example of an oral composition.

The application states that "abrasives" may be added to the compositions. As examples of abrasives, calcium pyrophosphate (p. 13 l. 1-5) and sodium bicarbonate are mentioned (p. 14 l. 5-9) among several others.

WO 03/002056 does not relate to the problem faced by the inventors of the present invention, i.e. more effective tooth whitening, nor does it give any hint to the solution found by the present inventors. The application does not comprise examples of confectionary comprising calcium pyrophosphate, let alone lozenges comprising calcium pyrophosphate, nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions as compared to other known abrasives.

**D2** (US 2003/072841) relates to "chewing gum" and "confectionary" comprising a polybutene with a molecular weight of 300 to about 3000. The objective problem solved hereby relates to the inhibition of the build-up of plaque and other debris on teeth.

The application does not mention "lozenges" among confectionary.

The compositions according to the application may contain "abrasive polishing materials" in an amount of 1%-70% and/or 5–50%. Calcium pyrophosphate is mentioned amongst numerous other abrasive agents.

The application does not comprise examples of confectionary comprising calcium pyrophosphate, let alone lozenges comprising calcium pyrophosphate, nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions as compared to other known abrasives.

**D3** (WO 03/017964) relates to oral compositions comprising an alkyl hydroxybenzoate. The objective problem solved hereby relates to the inhibition of bacterial growth by the anti-bacterial properties of the alkyl hydroxybenzoate.

Among several others, "lozenge" (p. 8 l. 15) is mentioned as an example of an oral composition.

Among several others, "calcium pyrophosphate" (p. 7 l. 14) is mentioned as an example of an abrasive agent which may optionally be added.

The application does not comprise examples of confectionary comprising calcium pyrophosphate, let alone lozenges comprising calcium pyrophosphate, nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions as compared to other known abrasives.

**D4** (WO 99/12517) relates to compositions for preventing the build-up of stain and whitening teeth and dental prostheses using a water soluble alkali metal tripolyphosphate in combination with an alkali metal pyrophosphate salt, and optionally polyvinyl pyrrolidone. The objective problem to be solved, e.g. whitening of teeth, is similar to the objective of the present application. The Applicant thus considers D4 to comprise the closest prior art.

"Lozenge" (p. 5 l. 16) is mentioned, among several others, as an example of an oral composition.

Calcium pyrophosphate is mentioned, among several others, as an example of an abrasive material (p. 9 l. 3).

The application does not comprise examples of confectionary comprising calcium pyrophosphate, let alone lozenges comprising calcium pyrophosphate, nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions for whitening teeth as compared to other known abrasives.

**D5** (US 2003/072722) relates to hydrogels for the whitening of teeth. The disclosure mentions the addition of agents which chelate metal ions. Sodium pyrophosphate is mentioned as such an agent.

The application does not relate to confectionary and does not mention calcium pyrophosphate, and is thus not considered to anticipate the present invention.

**D6** (DE 36 45 147 C2) relates to oral compositions, such as "chewing gum" and "lozenge" compositions containing an anticalculus agent. The oral composition preferably includes a "pyrophosphate salt" as a primary anticalculus agent (p.2 l. 36-37).

The patent does not mention calcium pyrophosphate nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions for whitening teeth as compared to other known abrasives.

**D7** (GB 1 018 665) relates to dentifrices that reduce enamel solubility. Calcium pyrophosphate in combination with a water-insoluble sodium metaphosphate is mentioned as a preferred polishing agent.

The patent does not comprise examples of confectionary comprising calcium pyrophosphate, let alone lozenges comprising calcium pyrophosphate, nor is it indicated therein that calcium pyrophosphate is especially useful in confectionary compositions as compared to other known abrasives.

Novelty

The Applicant considers the invention, defined by the above amended claims, to meet the criteria of Article 33(1) PCT and to be new in the sense of Article 33(2) PCT. This is substantiated below:

The present invention differs from the prior art in that the selection of calcium pyrophosphate as the whitening agent in lozenge compositions was surprisingly found to be superior to other conventional whitening agents.

Thus the present invention may be regarded as a "selection invention".

Common practice at i.e. the European Patent Office (EPO) is to allow so-called "selection inventions" directed to the selection of a specific sub-range from a known broad range or to a specific combination of concrete elements from two broad lists of known concrete elements (the "two-lists principle"). This is implemented in the Guidelines for Examination, Part C IV 7.7 which state:

*"In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualised (concrete) form in the prior art (see T 12/81, OJ 8/1982, 296). A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then the resulting combination of features, not specifically disclosed in the prior art, confers novelty (the "two-lists principle")".*

In the present case, the selection of calcium pyrophosphate as a suitable whitening agent from an extensive list of whitening agents, and confectionary, let alone lozenge, from a vast list of oral formulations provided by the above cited prior art references is clearly novel according to the "two-lists principle", adopted by the EPO.

According to the PCT Applicants Guide, novelty is to be acknowledged if the prior art does not anticipate the disclosed invention. The applicant is of the opinion that nothing in the prior art anticipates the present invention and that the invention is to be considered novel before e.g. the EPO. As case law similar to the practice at the EPO exists among a number of PCT contracting states and the invention is neither specifically disclosed nor hinted or anticipated by the prior art, the application is to be considered novel in the sense of article 33(2) PCT.

Inventive step:

The applicant considers the invention, defined by the above amended claims, to meet the criteria of Article 33(1) PCT and to involve an inventive step in the sense of Article 33(2) PCT. This is substantiated below:

The technical problem solved by the present invention is to provide an improved confectionary composition for whitening teeth. The solution was the formulation of a lozenge composition comprising calcium pyrophosphate, which was surprisingly found to have a significantly improved whitening effect compared to other commonly used abrasives. This effect is evident from the application as filed. However, in order to further substantiate this surprising effect, the Applicant has provided new supplementary experimental evidence, which is submitted as an appendix to this Demand.

As can be seen from these supplementary experiments calcium pyrophosphate is statistically significantly superior to other commonly used whitening agents, when used in a lozenge composition (se table 2 and corresponding figure 2).

The prior art referred to above fail to produce a single example of a confectionary composition comprising calcium pyrophosphate. Although calcium pyrophosphate is proposed as an abrasive agent in oral formulations and mentioned as such along with numerous other common whitening agents in some of the cited prior art documents, no hints can be found in the prior art as to any surprising beneficial effect of calcium pyrophosphate as a whitening agent, superior over other abrasive agents. Even more specifically the skilled person would not find any motivated guidance or directions as to the superior effect of the specific choice of calcium pyrophosphate in a lozenge composition.

D1-D7 alone or in combination fails to provide to the skilled person with more than the ubiquitous and standard phrasing of the possibility of using in dental compositions one or more of a range of known abrasive materials in order to achieve whitening of teeth. Thus, D1-D7 alone or in combination merely indicate that the selection of calcium pyrophosphate in a lozenge composition could possibly have a whitening effect.

As disclosed in the application and further substantiated by the additional experimental evidence provided by the applicant, the selection of calcium pyrophosphate in a lozenge composition not only has a tooth whitening effect, which may or may not have been expected, but has a whitening

effect which is superior to the effect impaired by other common whitening agents in a lozenge composition. This teaching cannot possibly be extracted from D1-D7, alone or in combination, and accordingly the present invention involves an inventive step.

The Applicant is therefore of the opinion that the subject-matter of the presently amended claims 1-21 involves an inventive step in the sense of Article 33(2) PCT.

In light of the above, the Examiner is respectfully requested to reconsider his opinion and issue an International Preliminary Examination Report acknowledging the patentability of the present invention. However, should the Examiner not agree with the Applicant's comments, we respectfully request a telephone interview with the Examiner.

Yours faithfully

Ulla C. Klinge

Representative of the Applicant

Encs.: Demand
Amended claims of October 2005
Draft showing the claim amendments in handwriting
Results from hard boiled candy whitening test
EPO form 1038
Voucher

Claims

1. A solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a lozenge base,

b) conventional lozenge additives,

c) a tooth whitening agent comprising calcium pyrophosphate.

2. A composition according to claim 1 in which said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

3. The composition according to claim 2 in which said calcium pyrophosphate is present in an amount of between 0.5% and 9%, preferably between 1.0 % and 6.5 %, even more preferably between 1.5 % and 4.0 %, by weight of the composition.

4. The composition according to any of the preceding claims in which said conventional lozenge ingredients comprise one or more of the following: sweeteners, high intensity sweeteners, taste enhancers, flavouring agents, colouring agents.

5. The composition according to any of the preceding claims in which said composition is essentially sugar-free.

6. The composition according to any of the preceding claims comprising one or more additional tooth whitening agents.

7. The composition according to claim 6 in which said additional tooth whitening agent(s) is/are present in between 0.01% and 5.0%, more particularly between 0.05 and 1.0%, most preferably between 0.1% and 0.5% by weight of the composition.

8. The composition according to claim 6 or 7 in which said additional tooth whitening agent comprises a bicarbonate salt.

9. The composition according to claim 8 in which said additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.1% and 0.5% by weight of the composition.

10. The composition according to any of the preceding claims in which said additives and/or tooth whitening agents are encapsulated.

11. The composition according to any of the preceding claims further comprising one or more of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitising agents, therapeutically active agents, remineralising agents.

12. The composition according to any of the preceding claims further comprising a supplement.

13. The composition according to claim 12 in which said supplement comprises vitamin C.

14. The composition according to claim 11 in which the oral hygiene promoting agent comprises urea, said urea being present in between 0.1% and 25%, particularly between 0.4% and 10%, preferably between 0.6% and 5.0%, more preferably between 0.7 % and 3.5%, even more preferably between 0.8 % and 2.5% by weight.

15. The composition according to any of the preceding claims in the form of hard-boiled lozenges.

16. A use of a composition according to any of the preceding claims to whiten tooth surfaces.

17. A use of a composition according to claims 1-15 to whiten tooth surfaces, said

tooth surfaces being discoloured after use of red wine or related products.

18. A use of a composition according to any of the claims 1-15 to whiten tooth surfaces, said tooth surfaces being discoloured after use of coffee-related products.

19. A method of whitening tooth surfaces by consuming a solid, oral tooth whitening lozenge composition according to any of claims 1-15.

20. A method of whitening tooth surfaces by consuming a solid oral tooth whitening lozenge composition according to claims 1-15, said tooth surfaces being discoloured after use of red wine or related products.

21. A method of whitening tooth surfaces by consuming a solid oral tooth whitening lozenge composition according to any of the claims 1-15, said tooth surfaces being discoloured after use of coffee-related products.

Claims

1. A solid oral tooth whitening ~~confectionary~~ composition comprising more than 75% by weight of solid materials, said composition comprising:

a) a ~~confectionary~~ base,

b) conventional ~~confectionary~~ additives,

c) a tooth whitening agent comprising ~~an alkaline or alkaline earth metal~~ pyrophosphate.

2. A composition according to claim 1 in which ~~said a tooth whitening agent comprises calcium pyrophosphate~~.

3. A composition according to claim 2 in which said calcium pyrophosphate is present in an amount of between 0.1 and 10% by weight of the composition.

4. The composition according to claim 3 in which said calcium pyrophosphate is present in an amount of between 0.5% and 9%, preferably between 1.0 % and 6.5 %, even more preferably between 1.5 % and 4.0 %, by weight of the composition.

5. The composition according to any of the preceding claims in which said conventional ~~confectionary~~ ingredients comprise one or more of the following: sweeteners, high intensity sweeteners, taste enhancers, flavouring agents, colouring agents.

6. The composition according to any of the preceding claims in which said composition is essentially sugar-free.

7. The composition according to any of the preceding claims comprising one or more additional tooth whitening agents.

8. The composition according to claim 6 in which said additional tooth whitening agent(s) is/are present in between 0.01% and 5.0%, more particularly between 0.05

and 1.0%, most preferably between 0.1% and 0.5% by weight of the composition.

8 ~~9~~. The composition according to claim ~~7~~ 6 or ~~8~~ 7 in which said additional tooth whitening agent comprises a bicarbonate salt.

9 ~~10~~. The composition according to claim ~~9~~ 8 in which said additional tooth whitening agent comprises sodium bicarbonate, said agent being present in between 0.1% and 0.5% by weight of the composition.

10 ~~11~~ 10. The composition according to any of the preceding claims in which said additives and/or tooth whitening agents are encapsulated.

11 ~~12~~. The composition according to any of the preceding claims further comprising one or more of the following: oral hygiene promoting agents, anti-calculus agents, anti-microbial agents, anti-inflammatory agents, desensitising agents, therapeutically active agents, remineralising agents.

12 ~~13~~. The composition according to any of the preceding claims further comprising a supplement.

13 ~~14~~. The composition according to claim ~~13~~ 12 in which said supplement comprises vitamin C.

14 ~~15~~. The composition according to claim ~~12~~ 11 in which the oral hygiene promoting agent comprises urea, said urea being present in between 0.1% and 25%, particularly between 0.4% and 10%, preferably between 0.6% and 5.0%, more preferably between 0.7 % and 3.5%, even more preferably between 0.8 % and 2.5% by weight.

Mdl ~~16~~. The composition according to any of the preceding claims ~~in the form of lozenges~~.

any of the preceding claims

15 17. The composition according to claim 16 in the form of hard-boiled lozenges.

16 18. A use of a composition according to any of the preceding claims to whiten tooth surfaces.

17 19. A use of a composition according to claims 1-15 to whiten tooth surfaces, said tooth surfaces being discoloured after use of red wine or related products.

18 20. A use of a composition according to any of the claims 1-15 to whiten tooth surfaces, said tooth surfaces being discoloured after use of coffee-related products.

19 21. A method of whitening tooth surfaces by consuming a solid, oral tooth whitening ~~confectionary~~ composition according to any of claims 1-15.

3 x 2 lozenge

15 20 22. A method of whitening tooth surfaces by consuming a solid oral tooth whitening ~~confectionary~~ composition according to claims 1-15, said tooth surfaces being discoloured after use of red wine or related products.

21 23. A method of whitening tooth surfaces by consuming a solid oral tooth whitening ~~confectionary~~ composition according to any of the claims 1-15, said tooth surfaces being discoloured after use of coffee-related products.

*The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below*

IPEA/ EPO

# PCT

**CHAPTER II**

## DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty.

For International Preliminary Examining Authority use only

| Identification of IPEA | Date of receipt of DEMAND |
|---|---|
| | |

**Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION**

Applicant's or agent's file reference: 80081 MBE/TR

| International application No. | International filing date *(day/month/year)* | (Earliest) Priority date *(day/month/year)* |
|---|---|---|
| EP2004/013963 | 09 December 2004 | 08 December 2003 |

Title of invention: A solid oral tooth whitening confectionary composition

**Box No. II APPLICANT(S)**

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country.)*

Cadbury Schweppes PLC
25 Berkeley Square
London W1J 6HB
England

Telephone No: +44 203 968 7736
Facsimile No.: +44 203 968 5654
Teleprinter No:
Applicant's registration No with the Office:

| State *(that is, country)* of nationality: | State *(that is, country)* of residence: |
|---|---|
| UK | UK |

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country.)*

Sørensen, Edith Trøst
5, Danasvej
DK-8700 Horsens
Denmark

| State *(that is, country)* of nationality: | State *(that is, country)* of residence: |
|---|---|
| DK | DK |

Name and address: *(Family name followed by given name, for a legal entity, full official designation. The address must include postal code and name of country.)*

| State *(that is, country)* of nationality: | State *(that is, country)* of residence: |
|---|---|
| | |

☐ Further applicants are indicated on a continuation sheet.



*See Notes to the demand form*

International application No
EP2004/013963

**Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The following person is ☒ agent ☐ common representative

and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination

☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier

Name and address: *(Family name followed by given name. for a legal entity, full official designation The address must include postal code and name of country)*

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Agent's registration No with the Office

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent

**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**

Statement concerning amendments:*

1 The applicant wishes the international preliminary examination to start on the basis of:

☐ the international application as originally filed

the description
- ☒ as originally filed
- ☐ as amended under Article 34

the claims
- ☐ as originally filed
- ☐ as amended under Article 19 (together with any accompanying statement)
- ☒ as amended under Article 34

the drawings
- ☒ as originally filed
- ☐ as amended under Article 34

2 ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed

3 ☐ Where the IPEA wishes to start the international preliminary examination at the same time as the international search in accordance with Rule 69.1(b), the applicant requests the IPEA to postpone the start of the international preliminary examination until the expiration of the applicable time limit under Rule 69.1(d)

4 ☐ The applicant expressly wishes the international preliminary examination to start earlier than at the expiration of the applicable time limit under Rule 54*bis* 1(a).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended

Language for the purposes of international preliminary examination: English

- ☒ which is the language in which the international application was filed
- ☐ which is the language of a translation furnished for the purposes of international search
- ☐ which is the language of publication of the international application
- ☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination

**Box No. V ELECTION OF STATES**

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT



*See Notes to the demand form*

Sheet No. 3

International application No
EP2004/013963

**Box No. VI CHECK LIST**

The demand is accompanied by the following elements, in the language referred to in Box No IV, for the purposes of international preliminary examination:

| | | | | For International Preliminary Examining Authority use only: received | not received |
|---|---|---|---|---|---|
| 1 | translation of international application | : | sheets | ☐ | ☐ |
| 2 | amendments under Article 34 | : | 3 sheets | ☐ | ☐ |
| 3 | copy (or, where required, translation) of amendments under Article 19 | : | sheets | ☐ | ☐ |
| 4. | copy (or, where required, translation) of statement under Article 19 | : | sheets | ☐ | ☐ |
| 5. | letter | : | 7 sheets | ☐ | ☐ |
| 6 | other *(specify)* Experimental Results | : | 4 sheets | ☐ | ☐ |

The demand is also accompanied by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ original separate power of attorney
3. ☐ original general power of attorney
4. ☐ copy of general power of attorney; reference number, if any:
5. ☐ statement explaining lack of signature
6. ☐ sequence listing in electronic form
7. ☐ tables in electronic form related to a sequence listing
8. ☐ other *(specify)*:

**Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE**

*Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand)*

Chas. Hude A/S

Ulla C Klinge
Representative of the Applicant

**For International Preliminary Examining Authority use only**

1. Date of actual receipt of DEMAND:

2 Adjusted date of receipt of demand due to CORRECTIONS under Rule 60 1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply

☐ The applicant has been informed accordingly

4 ☐ The date of receipt of the demand is WITHIN the time limit of 19 months from the priority date as extended by virtue of Rule 80 5

5 ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82

6 ☐ The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54*bis* 1(a) and item 7 or 8, below, does not apply

7. ☐ The date of receipt of the demand is WITHIN the time limit under Rule 54*bis*.1(a) as extended by virtue of Rule 80 5

8 ☐ Although the date of receipt of the demand is after the expiration of the time limit under Rule 54*bis*.1(a), the delay in arrival is EXCUSED pursuant to Rule 82

**For International Bureau use only**

Demand received from IPEA on:

Kopi till GKO 24/10-05

**CHAPTER II**

# PCT

## FEE CALCULATION SHEET

**Annex to the Demand**

| | |
|---|---|
| International application No EP2004/013963 | For International Preliminary Examining Authority use only |
| Applicant's or agent's file reference 80081 MBE/TR | Date stamp of the IPEA |

Applicant

Cadbury Schweppes PLC

### CALCULATION OF PRESCRIBED FEES

| | | | |
|---|---|---|---|
| 1. Preliminary examination fee | EUR 1530 | P | |
| 2 Handling fee *(Applicants from certain States are entitled to a reduction of 75% of the handling fee Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee )* | EUR 129 | H | |
| 3 Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box | EUR 1659 TOTAL | | |

### MODE OF PAYMENT

| | | | |
|---|---|---|---|
| [X] | authorization to charge deposit account with the IPEA (see below) | [ ] | cash |
| [ ] | cheque | [ ] | revenue stamps |
| [ ] | postal money order | [ ] | coupons |
| [ ] | bank draft | [ ] | other *(specify)* |

### AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT

*(This mode of payment may not be available at all IPEAs)*

IPEA/ EPO

[X] Authorization to charge the total fees indicated above

[X] *(This check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)* Authorization to charge any deficiency or credit any overpayment in the total fees indicated above

Deposit Account No : 28030014

Date: 6 October 2005

Name: Ulla C Klinge

Signature: Ulla C Klinge



*See Notes to the fee calculation sheet*

# Results from hard boiled candy whitening test

## 1 Introduction

Clean white teeth are considered to be desirable by most people in Western countries. Dull-looking, stained teeth are socially objectionable both on the basis of cosmetic appearance and also as an indication of poor oral hygiene. A stain-removing hard boiled candy which helps to keep teeth white may have a large appeal among the general public. Such a product would be especially beneficial and convenient for use immediately after consuming stain-inducing foods, coffee, tea, red wine and tobacco products. Since eating hard boiled normally take much longer than brushing your teeth, the reaction time is longer, which will make up for the short rubbing effect from the tooth brush.
A special laboratory method has been developed to determine the potential of the hard boiled candy to remove dental stains. The general experimental design consists of using a specially-designed mechanical mastication device to treat stained teeth with hard boiled candy.

The purpose of this study was to evaluate the whitening effect of hard boiled candy with different active ingredients as well as a placebo without any active ingredients.

## 2 Methods & materials

### 2.1 Ingredients used

We used 6 different hard boiled candy all made by Cadbury EMEA, Table 1

Table 1. Hard boiled candy active ingredients used in the whitening test

| Product |
|---|
| 100-Cacium phosphate |
| 101-Aluminium phosphate |
| 102-Calcium silicate |
| 103-Sodiumhydrogen phosphate monohydrate |
| 104-Calcium Pyrophosphate |
| 105-Placebo |

### 2.2 Specimens was prepared by Carl Kleber

Squares of bovine dental enamel were embedded in clear polyester casting resin to provide 1.5 cm square blocks with the labial surface exposed. The specimens were rinsed with deionised water and attached to a staining apparatus in preparation for stain formation.
The tooth staining apparatus was designed to provide alternate immersion into the staining broth and air-drying of the specimens.
The staining broth was prepared by adding 1.02 g of instant coffee, 1.02 g of instant tea; 10 ml of red wine, and 0.75 g of gastric mucin to 250 ml of sterilised trypticase soy broth. Approximately 50 ml of a 24-hour *Micrococcus luteus* culture was also added to the stain broth. The apparatus, with the enamel specimens attached and the staining broth in the trough was then placed in an incubator at 37°C with the specimens rotating continuously through the staining broth and air.

The staining broth was replaced once every 24 hours. With each broth change, the trough and specimens were rinsed and tooth brushed with deionised water to remove any loose deposits.

### 2.3 Stain Measurement:

The amount of stain on the teeth was measured by taking colour readings with a Minolta spectrophotometer CM-2600d. Measurements over the entire visible colour spectrum were obtained using the CIELAB colour scale. This scale quantifies colour according to 3 parameters, L* (white-black value), a* (red-green value), and b* (yellow-blue value). In order to obtain reproducible readings, the stained enamel specimens were allowed to air-dry at room temperature for 30 minutes before colour measurements were made. At the end of a test period the stain was removed with sandpaper grain 600, in order to measure how much stain was available to remove.

Measurements were obtained by aligning the centre of the 4-mm square segment of stained enamel directly over the 3-mm-diameter targeting aperture of the Minolta spectrophotometer. An average of 3 colour readings using the L *a*b* scale were taken for each specimen.
L* 100 = perfect white

### 2.4 Study design

The hard boiled candy was dissolved in $dH_2O$. One part hard boiled candy was dissolved in three parts $dH_2O$ to stimulate salivary dilution in the mouth. 10 ml candy solution was placed in a XX ml bowl with one specimen at the bottom and placed in a shaking bench for 20 minutes. This step was repeated 5 times with fresh lozenge solution for each specimen. In between each step the teeth was measured with the Minolta as described in section 2.2. The total treatment time was 100 minutes.
In order to find significant differences 8 specimens was used, each with 5 repeated steps of 20 minutes.

The difference in whiteness is measured qualitatively using a colorimeter.

The stain removal procedure is illustrated in Figure 1.

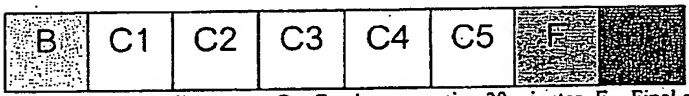


Figure 1 B – Baseline score C – Candy preparation 20 minutes F – Final stain score of remaining stain T – Total cleaning

## 3 Results

After treatment of all the specimens, we compared them in order to find a significant different between them, and to see which one had the highest whitening effect.

The stain calculations were done by the formula:

$$\% \text{ stain removal at } T_n = (E \text{ at } T_n / E \text{ max difference}) * 100$$

The overall change in the colour of the stained teeth was calculated using the CIELAB equation $\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$. The individual component L* (white) of the L*a*b* scale were also compared separately to determine the specific changes in the whiteness.

Data was tabulated using a spreadsheet program (Excel®, Microsoft), and analysed by means of conventional statistics.
Statistical significance of data for each category was determined by using a 2-tail T-test $p<0.05$.

The whitening effect was highest when calcium pyrophosphate was used, the stain reduction was measured to 20.45 % which was almost twice the reduction retained with the other whitening ingredients.

Besides Calcium pyrophosphate, sodium phosphate showed a significant stain removal effect compared to a placebo hard boiled candy.

Table 2. Results showing the differences in the overall colour change (ΔE) after 60 minutes treatment
ΔE max is the overall possible colour change and % stain reduction is stain removed/total stain

| | Δ E | Δ E max | % stain reduction |
|---|---|---|---|
| 100-Cacium phosphate | $3,04 \pm 2,04^{bc}$ | $30,23 \pm 4,70^{a}$ | $9,61^{bc}$ |
| 101-Aluminium phosphate | $2,10 \pm 0,81^{bc}$ | $32,70 \pm 6,27^{a}$ | $6,60^{bc}$ |
| 102-Calcium silicate | $1,98 \pm 1,34^{bc}$ | $36,13 \pm 7,82^{a}$ | $5,29^{bc}$ |
| 103-Sodium phosphate | $3,30 \pm 0,30^{b}$ | $31,20 \pm 3,44^{a}$ | $10,59^{b}$ |
| 104-Calcium pyrophosphate | $7,05 \pm 1,25^{a}$ | $35,33 \pm 4,94^{a}$ | $20,45^{a}$ |
| 105-Placebo | $2,42 \pm 1,69^{bc}$ | $33,07 \pm 7,79^{a}$ | $6,87^{bc}$ |
| $dH_2O$ | $1,62 \pm 0,15^{c}$ | $29,59 \pm 1,52^{a}$ | $5,51^{c}$ |

The results shown in Table 2 are illustrated in Figure 2. The samples in group 104-Calcium pyrophosphate give a significant better all over colour change, and are the most effective in whitening the teeth specimens.

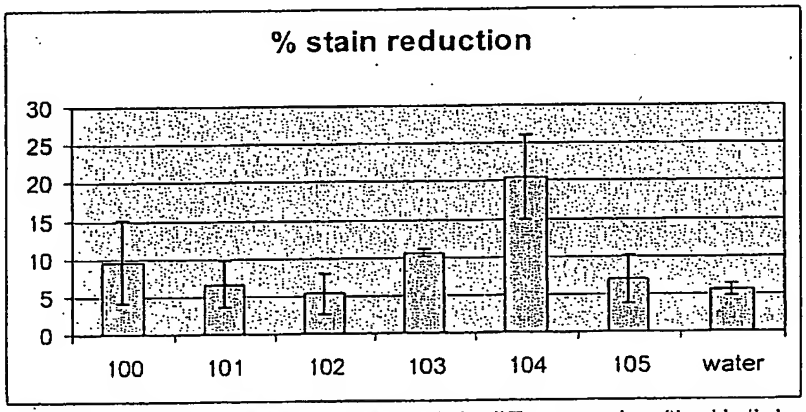


Figure 2 The stain removed by treatment with the different samples of hard boiled candy

When the repeated tests were done, all specimens were polished in order to gain the total stain removal that could be done ($E_{max}$) the total whitening was calculated from this measurement. These results are shown in Figure 3.
As the graph shows there is not significance between the groups, hence the possible stain removal is the same.

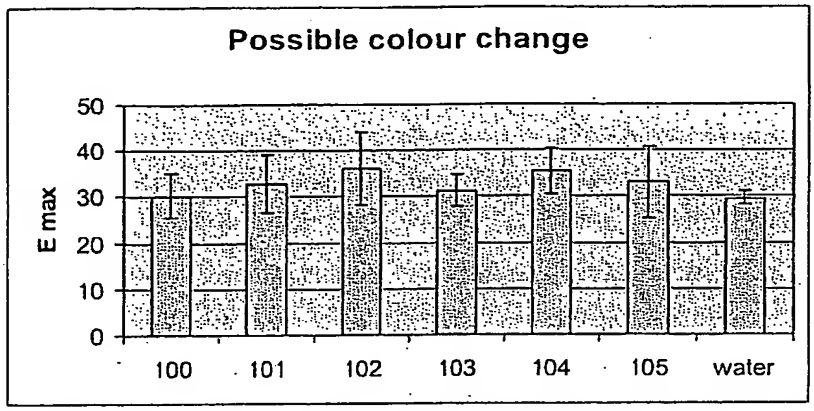


Figure 3 The total stain on the teeth specimens in the different groups which also is the maximal possible colour change

## 4 Conclusion

The total amount of stain removed from the specimens was significant better when the calcium pyrophosphate was used compared to all the other samples.
The total stain removed with calcium pyrophosphate was 20.45% compared to only 5.29% and 10.59% when the other ingredients was used.

The $\Delta E_{max}$ values in Figure 2 are not significant different which implies that the amount of stain available for removal was the same in the different groups.

In general there are considerable deviations in the results. The reason for that is not clear but it could be due to the spectrophotometer even though it was calibrated at the beginning of each day and sometimes during the day.

The change in colour between chewing was obvious to the eye. C. Kleber has mentioned that a $\Delta E$ around 1 can be detected by the human eye.